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SECTION 9
510(K) SUMMARY

FOI RELEASABLE

1. Submitter:

SaiNath Intellectual Properties, LLC
9438 Pebble Beach Ct. West
Seminole, FL 33777
Telephone: 813-222-1190
Fax: 813-229-8313

Contact: Christopher Paradies
Date Prepared: January 18, 2010

2. Device:

Trade Name: IYUNNI™ 3ID Tri-Funnel Feeding Tube Kit
Classification Name: 78 KNT Gastrointestinal Tube & Accessories
Regulation Number: 876.5980
Product Code: KNT
Classification: Class II

3. Predicate Device:

IYUNNI™ 3ID Tri-Funnel Gastrostomy Tube Kit, K092049
Bard® Dilation Kit with Tri-Funnel Gastrostomy Tube, K063118
Kimberly-Clark* Introducer Kit, K080253

4. Device Description:

The IYUNNI™ 3ID Tri-Funnel Gastrostomy Tube Kit is a percutaneous endoscopic gastrostomy tube kit comprising the Bard® Tri-Funnel Gastrostomy Tube along with the IYUNNI™ Soft Tip Introducer Dilator. Now, SaiNath Intellectual Properties intends to introduce its own gastrostomy tube as part of this kit. The Bard® Tri-Funnel Gastrostomy Tube is an all silicone tube with a balloon as the internal bolster and a silicone external bolster. The IYUNNI™ 3ID Tri-Funnel Feeding Tube kit will include, in addition to a gastrostomy tube the IYUNNI™ Soft Tip Introducer Dilator and a silicone external bolster.

5. Intended Use:

The IYUNNI™ 3ID Tri-Funnel Feeding Tube Kit is indicated for use in percutaneous placement of a gastrostomy tube for feeding and/or medication in conjunction with an established gastrostomy tract. The gastrostomy tube may also be used for gastric decompression.

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6. Technological Characteristics

The proposed IYUNNI™ 3ID Tri-Funnel Feeding Tube Kit is the same design, materials, and manufacturing processes of the predicate IYUNNI™ 3ID Tri-Funnel Gastrostomy Tube Kit (K092049).

7. Performance Data:
Testing has been performed and all components, subassemblies, and/or full devices met the specifications for the completed tests, including performance bench testing balloon inflation testing, and biocompatibility testing of the non-latex polyurethane film, which is the same material used in the predicate device.

8. Conclusion:
SaiNath Intellectual Properties, LLC has demonstrated that the proposed IYUNNI™ 3ID Tri-Funnel Feeding Tube Kit is substantially equivalent in intended use and indications to the predicate devices, IYUNNI™ 3ID Tri-Funnel Gastrostomy Tube Kit, K092049; Bard® Dilation Kit with Tri-Funnel Gastrostomy Tube, K063118; Kimberly-Clark* Introducer Kit, K080253. Technological differences have been qualified through biomaterial assessments and bench testing, the result of which did not raise new safety or performance questions.

Figure 9-1 compares the descriptive characteristics of these products. As demonstrated in Figure 9-1, the IYUNNI™ 3ID Tri-Funnel Feeding Tube Kit is equivalent in its indications for use, design, and materials.

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SECTION 6
KIT CERTIFICATION

I certify that the following components of my kit are either (1) legally marketed pre-amendments devices, (2) exempt from premarket notification (consistent with the exemption criteria described in the classification regulation(s) and the limitations of exemptions from Section 510(k) of the act (e.g., 862.9) or (3) have been found to be substantially equivalent through the premarket notification process for the use(s) for which the kit is to be intended (i.e., I am not claiming or causing a new use for the component(s)).

The IYUNNI™ 3ID Tri-Funnel Feeding Tube Kit marketing clearance is subject to this 510(k), but is however, a kit including a currently marketed gastrostomy tube preassembled with a soft tip introducer dilator, which has been found substantially equivalent.

I further certify that the component of this kit, of which the component is listed below, will be either purchased in bulk or pre-packaged in a single unit dosage when reasonably available. These items will be assembled in a tray, sealed Tyvek container and sterilized prior to shipment. Each kit will contain a preassembled soft tip introducer dilator inserted in a gastrostomy tube.

I.V.S. Nath

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR 16 2010

Mr. I.V.S. Nath
President
SaiNath Intellectual Properties LLC
9438 Pebble Beach Ct. West
LARGO FL 33777

Re: K100173
Trade/Device Name: IYUNNI™ 31D Tri-Funnel Feeding Tube Kit
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: January 18, 2010
Received: January 21, 2010

Dear Mr. Nath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

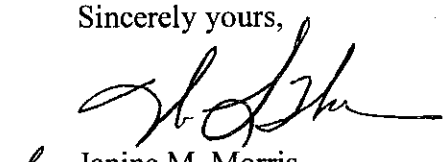
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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C. INDICATIONS FOR USE

510(k) Number (if known): ~~To Be Determined~~ K100173

Device Name: IYUNNI™ 3ID TRI-FUNNEL FEEDING TUBE KIT

Indications for Use:

The IYUNNI™ 3ID Tri-Funnel Feeding Tube Kit is indicated for use in percutaneous placement of a gastrostomy tube for feeding and/or medication using a Percutaneous Endoscopic Gastrostomy procedure. The gastrostomy tube may also be used for gastric decompression.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K100173